

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-17, drawn to an anti-reflux valve.

Group II, claim(s) 18-24, drawn to a method of treating gastroesophageal reflux.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: a method for treating comprises implanting the valve and does not require to locate and secure a valve at the oesophagal sphincter muscle as claimed.

During a telephone conversation with Richard Mescher on 12/05/2008 a provisional election was made without traverse to prosecute the invention of group I, claims 1-17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 18-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-12 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kilcoyne et al (US Patent 6,264,700; hereinafter Kilcoyne).

***With respect to claims 1-3, 9-10;*** Kilcoyne discloses a valve (20) that permits unidirectional flow and allows reverse flow when a pressure meets a certain threshold. (column 7, lines 18-26 and 40-56). The valve comprises a retention means (namely an anchor, 18) which secures the valve into a wall. The material used allows the valve to be flexible and collapsible (column 2, lines 39-48) and is biodegradable.

***With respect to claims 5-8, 11-12;*** Kilcoyne discloses a retention means, or more specifically a flange (namely an anchor, 18, which qualifies as a flange, which is a retention means) where the flange may contain an adhesive. (column 4, lines 16-32). Further, the flange defines a conduit, where the flange comprises apertures (38). The valve is to be positioned with the retention members against the wall (abstract) and is distensible due to the material used and is adapted to be clamped to the wall.

***With respect to claims 15-17;*** Kilcoyne discloses the claim limitations as claimed above; further, a dispensing or insertion means (namely a tubular introducer)

which is an elongated tube adapted to receive and dispense or insert the device into the stomach. (column 10, lines 3-25).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne as applied to claims 1, 11, and 12 above, and further in view of Taylor (US Patent 6,254,642).

***With respect to claim 4;*** Kilcoyne discloses the invention substantially as claimed. However, Kilcoyne does not disclose a mitral valve. Taylor discloses a mitral valve (column 6, lines 20-39) for the purpose of easier implantation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to

modify Kilcoyne's valve with the teachings of Taylor with respect to the mitral valve in order to allow for easier implantation.

***With respect to claims 13-14;*** Kilcoyne discloses the invention substantially as claimed. However, Kilcoyne does not disclose a tether detachably engageable with the distensible element to allow the element to be drawn against the stomach, further with an inflatable balloon. Taylor discloses an inflatable balloon to allow the element to be drawn against the stomach wall (column 2 & 3) for the purpose of allowing the retention members (namely the anchors) engage with the wall during implantation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kilcoyne with an inflatable balloon in order to engage the retention members with the wall during implantation.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. BOOTH whose telephone number is (571)270-7027. The examiner can normally be reached on Monday thru Thursday 8:00am - 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. B./  
Examiner, Art Unit 3774  
February 3, 2009

/Alvin J Stewart/  
Primary Examiner, Art Unit 3774